IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

LAURENCE ALLEN AND MICHELLE ALLEN, AS THE CO-ADMINISTRATORS OF THE ESTATE OF JOHN BRADLEY ALLEN,

Plaintiff,

Case No.: 1:16-CV-1538 (DNH/CFH)

v.

INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC.; RECKITT BENCKISER HEALTHCARE (UK) LTD.; INDIVIOR PLC, f/k/a RECKITT BENCKISER GROUP plc; and MONOSOL RX, LLC

Defendants.

COMPLAINT

Laurence and Michelle Allen, as Co-Administrators of the estate o f J. Bradley Allen, complain against Defendants Indivior Inc. f/k/a/ Reckitt Benckiser Pharmaceuticals, Inc.; Reckitt Benckiser Healthcare (UK) LTD.; and Indivior PLC, f/k/a Reckitt Benckiser Group, PLC (collectively "Reckitt" or "Reckitt Defendants": and MonoSol Rx, LLC ("MonoSol") as follows:

NATURE OF ACTION

1. This is an action in law seeking relief under Connecticut's products liability and unfair trade practices statutes for damages caused by Defendants' design, manufacturing, marketing, selling and distribution of the prescription drug Suboxone ("suboxone") and its generic equivalent, co-formulated buprenorphine hydrochloride and naloxone hydrochloride dehydrate ("co-formulated buprenorphine/naloxone").

2. Plaintiff brings this action with respect to the prescription drug Suboxone ("suboxone") and its generic equivalent, co-formulated buprenorphine hydrochloride and naloxone hydrochloride dehydrate ("co-formulated buprenorphine/naloxone").

3. Co-formulated buprenorphine/naloxone is a combination drug product consisting of two active pharmaceutical ingredients that are used together as an opioid replacement therapy for the treatment of opioid dependency (e.g., addiction to opioid-based pharmaceuticals). Defendants are engaged in the manufacture or sale of co-formulated buprenorphine/naloxone under the brand-name Suboxone.

4. Plaintiff alleges that the Defendants were negligent in both their design and labeling of Suboxone and that, as a result, it caused crippling addiction to J. Bradley Allen and, upon his prescribed supply ending, violent withdrawal symptoms. In order to cope with the severe withdrawal, he turned to heroin, and an overdose killed him in the late evening to early morning hours of January 31, 2014 to February 1, 2014.

JURISDICTION AND VENUE

5. The Court has federal question and supplemental jurisdiction pursuant to 28 U.S.C. § 1331. The Court also has diversity jurisdiction pursuant to 28 U.S.C. § 1332, as the estate of Mr. Allen is and was located in the state of Connecticut and the defendant is located in the State of New Jersey.

6. Venue properly lies in this Court under 28 U.S.C. §1391. Each Defendant transacts business or committed an illegal or tortious act in this district, or has an agent that can be found in this district. Additionally, the events and omissions giving rise to Plaintiff's claims occurred within this judicial district. The Defendant is a publically traded company, incorporated in Delaware and with its principal place of business in the State of New Jersey.

PARTIES

7. Defendant Indivior f/k/a Reckitt Benckiser Pharmaceuticals, Inc. ("Reckitt") is a Delaware Corporation with its principal place of business located at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235. Reckitt Benckinser Group, Inc. was demerged from its prior parent, the Reckitt Benckiser Group PLC, into Indivior PLC in December 2014 Indivior Inc. is a wholly-owned subsidiary of Indivior PLC. Indivior Inc. is engaged in the development, manufacture and sale of pharmaceuticals, including Suboxone, and health care products and services throughout the United States, and is in whole or in part responsible for some or all of the conduct alleged in this Complaint and attributed to Reckitt.

8. Defendant Reckitt Benckiser Healthcare (UK) Ltd. is a British corporation incorporated under the laws of England and Wales, with its registered office located at 103-105 Bath Road, Slough, Berkshire, SL1 3UH. This defendant is engaged in the development and manufacture of pharmaceuticals, including Suboxone, and health care products and services ' made and sold subject to FDA approval, and is in whole or in part responsible for some or all of the conduct alleged in this Complaint and attributed to Reckitt.

9. Defendant Indivior PLC, was formerly part of Reckitt Benckiser Group plc, and is a British corporation incorporated under the laws of England and Wales, with its registered office located at 103-105 Bath Road, Slough, Berkshire, SLI 3UH. This defendant is engaged in the development, manufacture, and sale of pharmaceuticals, including Suboxone, and health care products and services throughout the United States, and is in whole or in part responsible for some or all of the conduct alleged in this Complaint and attributed to Reckitt. Indivior PLC is the successor in interest to Reckitt Benckiser Group pic. Unless identified individually, Indivior Inc. and Indivior PLC are collectively referred to as "Reckitt."

10. Defendant MonoSol Rx, LLC is a Delaware limited liability company with its principal place of business located at 6560 Melton Road, Portage, Indiana, 46368. Defendant is engaged in the development, manufacture, and sale of pharmaceuticals and health care products and services throughout the United States, and is in whole or in part responsible for some or all of the conduct alleged in this Complaint and attributed to MonoSol.

11. Plaintiff is the father of the now-deceased J. Bradley Allen and one of the co-Administrators of his son's estate. John Bradley Allen, the deceased, was born in 1994 and died in the early morning hours of January 31 into February 1, 2014. At the time of his death, he was suffering from withdrawal from the cessation of taking Suboxone, to which he had become addicted. His resulting death, from a heroin overdose, came just a few weeks after his prescription ran out.

BACKGROUND

12. John Bradley Allen ("Brad") was injured in a car accident in 2010, and his doctors at the time, as part of a pain management program, prescribed him hydrocodone.

13. Brad, at some point into his prescribed opioid regimen, became dependent on the opioid-based medication.

14. Beginning in February 2012, in order to transition Brad off of his dependency on the prescription opioid, he was prescribed suboxone by his physician.

15. Brad began taking a dose of 2 milligrams of suboxone a day and continued, without interruption, for the next twenty months to take at least that amount daily.

16. At the time Brad started taking suboxone, he was a week shy of his eighteenth birthday.

17. By late 2013, Brad had become completely addicted to suboxone, a pharmaceutical that is designed to treat opioid addiction. That is, he replaced on addiction with another.

18. In December 2013, Brad attempted to end his suboxone usage and enrolled in an intensive in-patient program to help him through the withdrawals.

19. His last prescribed dose was on or about December 27, 2013.

20. After completing the 21-day program, Brad went home to his family.

21. On or about January 31, 2014, after watching a movie with his family, Brad went upstairs to his room, ingested heroin, overdosed and died. His parents found him the next morning.

22. At the time of his death, J. Bradley Allen was a successful college student who was in the midst of an investment banking internship at NYPPEX, a private equity advisement firm located in the State of New York.

23. As a result of his suboxone addiction, Bradley Allen suffered through the pain of addiction, which eventually led to his debilitating withdrawals. The only way to treat those withdrawals was with heroin, and his death from an overdose was a direct result of his addiction.

CAUSES OF ACTION
COUNT I: NEGLIGENCE

24. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

25. At all times relevant to this action, Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion and sale of suboxone

which Defendants introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous or untoward adverse side effects.

26. At all times relevant to this action, Defendants had a duty to warn all health care providers and consumers of the risks, dangers, and adverse side effects of suboxone and co-formulated buprenorphine/naloxone.

27. At all times relevant to this action, Defendants knew or reasonably should have known that suboxone and co-formulated buprenorphine/naloxone were unreasonably dangerous and defective when used as directed and as designed, including but not limited to the following particulars;

28. The regular use of these medications causes addiction and makes the cessation of these medications impossible;

29. Based on what they knew or reasonably should have known as described above, the Defendants deviated from principles of due care, deviated from the standard of care, and were otherwise negligent in one or more of the following particulars:

a. In failing to conduct those tests and studies necessary to determine that the use of suboxone and co-formulated buprenorphine/naloxone was dangerous to patients;

b. In failing to instruct or warn the medical community that the safety of the suboxone and co-formulated buprenorphine/naloxone had not been established for use, especially by young adults;

c. In failing to disclose to the medical community that suboxone and co-formulated buprenorphine/naloxone, may cause serious and permanent injury including but not limited to addiction;

d. In failing to provide to the medical community adequate instructions for the safe use of suboxone and co-formulated buprenorphine/naloxone;

e. In failing to disclose to the medical community that the effectiveness of suboxone and co-formulated buprenorphine/naloxone

f. Manufacturing a product designed to deliver, over time, dangerously high doses of medication.

30. At all relevant times, Defendants knew or reasonably should have known that the suboxone and co-formulated buprenorphine/naloxone were unreasonably dangerous and defective when used as directed and designed, including but not limited to the following particulars:

a. Suboxone was habit-forming and lacked the proper protocols for its use.

31. The product defects alleged above were a substantial contributing cause of the injuries and damages suffered by Plaintiff.

32. The injuries and damages suffered by Plaintiff were the reasonably foreseeable results of Defendants' negligence.

33. Had Defendants performed those tests and studies necessary to determine that their product should not be used indiscriminately and without a proper regimen, Brad would not have developed his addiction and suffered the injuries and damages described with particularity above.

34. As a direct and proximate cause of the Defendants' negligence, Plaintiff's addiction issues and its related conditions, including but not limited to severe pain and discomfort and associated mental trauma. In addition, Plaintiff suffered mental distress and anguish and has, as a direct result of the addiction, withdrawal and attempts at abstinence, been forced to self-medicate with illegal narcotics. Such self-medication led, quickly, to his death.

COUNT II: STRICT LIABILITY

35. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

36. Plaintiff is in the class of persons that the Defendants should reasonably foresee as being subject to the harm caused by defectively designed pharmaceuticals insofar as Plaintiff was the type of person for whom the suboxone and co-formulated buprenorphine/naloxone and the pharmaceuticals in question were intended to be used.

37. Defendants, which are engaged in the business of selling the products, manufactured and supplied suboxone and co-formulated buprenorphine/naloxone and placed them into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

38. The suboxone and co-formulated buprenorphine/naloxone supplied to Plaintiff were defective in design and formulation and unreasonably dangerous when they left the hands of Defendants, the manufacturers and suppliers, and they reached the user and consumer of the products, Plaintiff, without substantial alteration in the condition in which they were sold.

39. The suboxone and co-formulated buprenorphine/naloxone manufactured by Defendants were unreasonable and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding these products.

40. Defendants' suboxone and co-formulated buprenorphine/naloxone were defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results of such studies.

41. Defendants' products were defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury, including addiction, from their pharmaceutical, they failed to provide adequate warnings to the medical community and patients, and continued to promote the products as safe and effective.

42. The product defects alleged above were a substantial contributing cause of the injuries suffered by Plaintiff. Specifically, the pharmaceuticals in question caused Plaintiff to suffer through addiction, in direct contradiction to the addiction relief it promised, resulting in severe pain and discomfort, nausea, associated mental disabilities and loss of the enjoyment of life. Upon the cessation of the use of the pharmaceutical, Brad suffered from severe withdrawal symptoms which forced him to self-medicate with illegal narcotics.

43. As a direct and proximate cause of the Defendants' negligence, Plaintiff suffered through addiction, in direct contradiction to the addiction relief it promised, resulting in severe pain and discomfort, nausea, associated mental disabilities and loss of the enjoyment of life. Upon the cessation of the use of the suboxone, Brad suffered from severe withdrawal symptoms which forced him to self-medicate with illegal narcotics. In addition, Plaintiff suffered lost wages and lost earning capacity, mental distress and anguish and eventually an overdose and death.

COUNT III
STRICT PRODUCTS LIABILITY: FAILURE TO WARN

44. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

45. Defendants manufactured suboxone and co-formulated buprenorphine/naloxone, and placed them into the stream of commerce in a defective and unreasonably dangerous

condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

46. Defendants' suboxone and co-formulated buprenorphine/naloxone were defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results.

47. Defendants' suboxone and co-formulated buprenorphine/naloxone were defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from their suboxone and co-formulated buprenorphine/naloxone, they failed to provide adequate warnings to the medical community and patients, and continued to promote the product as safe and effective.

48. The defective warnings and labeling on the pharmaceuticals in question were substantial factors in bringing about the injuries to the Plaintiff.

49. As the direct and proximate cause of the defective condition of the product as manufactured and/or supplied by Defendants, and specifically their failure to warn, and their negligence, carelessness, other wrongdoing and actions described herein, Plaintiff suffered those injuries and damages as described with particularity, above.

50. As a direct and proximate cause of the Defendants' negligence suffered through addiction, in direct contradiction to the addiction relief it promised, resulting in severe pain and discomfort, nausea, associated mental disabilities and loss of the enjoyment of life. Upon the cessation of the use of the pharmaceutical, Brad suffered from severe withdrawal symptoms which forced him to self-medicate with illegal narcotics. In addition, Plaintiff suffered lost wages and lost earning capacity, mental distress and anguish and eventually an overdose and death.

PRAYER FOR RELIEF

51. WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, for One Hundred Million Dollars ($100,000,000) compensatory damages, plus interest, costs and attorneys' fees.

52. That this Court award Plaintiff his costs and expenses incurred in this action, as well as such other and further relief as the Court deems just and proper.

JURY DEMAND

53. Plaintiff demands a trial by jury as to all issues herein presented.

Dated: December 19, 2016

THE KINDLON LAW FIRM, PLLC

By: s/Lee C. Kindlon

Attorney for Plaintiff
74 Chapel Street
Albany, New York 12207
Telephone: (518) 434-1493
Fax: (518) 935-9336
E-mail: lkindlon@kindlon.com